

K132616 EPADJan 24, 2014
156 days to decisionK132616 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k132616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Aug 21, 2013
Decision date	Jan 24, 2014
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Safeop Surgical, Inc.
Location	Amherst, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	2 submissions · 2 cleared · 2014-2019

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